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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,222	01/12/2001	John R. Liddicoat	VIA-14	1731

7590

10/03/2003

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT PAPER NUMBER

3738

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Appli ation No.

09/760,222

Applicant(s)

LIDICOAT ET AL.

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: **BEST AVAILABLE COPY**

**DETAILED ACTION**

***Response to Arguments***

1. Applicant's arguments with respect to claims 1-17 and 28 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-10, 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell US PN 6,102,945 in view of Hata et al. US PN 5,769,780.

Campbell discloses in Figure 3 an annuloplasty band comprising a ring of material 122 having both external (cloth covering) and metallic internal 26 axial support structures. Figures 4-5 show opposed ends of segment 112, which is flexible and capable of allowing connection between the opposed ends.

Regarding claim 13, lines 1-20 describe an axial structure of suture material.

Campbell describes the ring of material 122 as biocompatible and flexible silicone, but lacks the express written disclosure of using tissue material. Hata et al. teaches in lines 19-33 of col. 4 (and throughout the description) that it is well known to use natural tissue for annuloplasty rings because of the enhanced biocompatibility,

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lower profile, and durability. Hata et al. teaches the use of pericardial and autologous tissue.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the annuloplasty band disclosed by Campbell by using autologous or pericardial tissue, as taught by Hata et al., as a replacement for silicone in order to provide a more biocompatible, durable, and lower profiled annuloplasty band.

4. Claims 11 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell US PN 6,102,945 in view of Hata et al. US PN 5,769,780, as applied to claims 1 and 4-8 above, and further in view of Loch et al. US PN 6,174,332.

Regarding claim 11, the device disclosed by Campbell as modified by Hata et al. lacks the express written disclosure of utilizing plastic for the internal support member (26, Fig 3 of Campbell). With regard to claim 28, the device disclosed by Campbell as modified by Hata et al. lacks the express written disclosure of utilizing adhesive for the graft tissue. Loch et al. teaches in lines 38-52 of col. 3 annuloplasty bands having either plastic or metal structural supports and adhesives to prevent fraying and maintain the integrity of the structure.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the annuloplasty band disclosed by Campbell, as modified by Hata et al., by selecting plastic and using adhesive as taught by Loch et al. in order to provide structural support and prevent fraying.

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5. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell US PN 6,102,945 in view of Hata et al. US PN 5,769,780, as applied to claims 1,4,14-16 above, and further in view of Sherman et al. US PN 5,891,159.

Campbell as modified by Hata et al. teaches the structure of claim 17 (as well as suturing the device to the annulus) but lacks the express written disclosure of the external support comprising purse string sutures. Sherman et al. teaches in lines 13-19 of col. 1 that it is well known in the art of cardiac surgery to use purse string sutures to attach devices to circular shapes.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Campbell, as modified by Hata et al., by using purse string sutures as taught by Sherman et al. to attach the annuloplasty band to the annulus.

### ***Conclusion***

6. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 7-21-03 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Tue-Fri 8:00-6:30 (Every Monday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



WHM  
September 30, 2003



CORRINE McDERMOTT  
SUPERVISORY PATENT EXAMINER  
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